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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,330	01/29/2007	Joseph L. Witztum	1034123-000170	6646

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EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,330	WITZTUM ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *15-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-32 are pending.

2. Applicant's election without traverse of Group I (drawn to claims 1-14 and 26-32) and an elected species of 1-palmitoyl-2-oxovaleroyl-sn-glycero-3-phosphoryl-choline (POVPC) in the reply filed on 10/6/08 and 3/16/09 is acknowledged.

Accordingly, claims 15-25 are withdrawn from further consideration by the examiner 37 CFR 1.142 (b) as being drawn to a nonelected invention.

Claims 1-14 and 26-32 are under consideration in the instant application.

3. Applicants' submission of IDS filed on 1/19/06 has been acknowledged.

4. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). In p.3 of the oath filed on 1/8/07, the address is modified without an initial.

5. Claims 5 and 32 are objected to because of the following informalities: A typographic error is noted in "lipotechoic acid". Appropriate correction is required.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6-8, 13, 14, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/10203 as is evidenced by Shaw et al (J. Clnical. Invest., vol. 105, p. 1731-1740, IDS reference).

The '203 publication teaches administration of a vaccine composition comprising a phosphatidylcholine and an adjuvant (claims 1-24) in human and the vaccine composition treats atherosclerosis (abstract, claim 23-24, p. 1-3).

As is evidenced by Shaw et al. a phosphatidylcholine comprises two fatty acid chains and a phosphorylcholine headgroup (p. 1731, 2nd col.), the referenced vaccine composition comprising "phosphatidylcholine" inherently includes a phosphorylcholine headgroup. Therefore, the claimed limitation of "phosphorylcholine enriched preparation" has been met.

Note that the claimed method recites administering a product made by a particular process. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by different process. *In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964 966 (Fed. Cir. 1985). See MPEP 2113. Given that the prior art composition and the recited product by process composition comprise phosphatidylcholine, the structural limitations of the administered composition have been met.

Where the claimed and prior art products are identical or substantially identical in structure or composition or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best* (562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the

applicant has the burden of showing that they are not. *In re Spada* (911 F.2d 705, 709, 15 USPQ 2d 1655, 1658 (Fed. Cir 1990). See MPEP 2112.01.

Given that the referenced and the recited "phosphorylcholine enriched preparation" appear to be identical from the evidence of record, the administration of the referenced composition inherently results in the production of antibodies that bind to oxidized low density lipoprotein (oxLDL).

Therefore, the reference teachings anticipate the claimed invention.

8. Claims 1, 2, 6-8, 13, 14, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,455,032.

The '032 patent teaches a method of vaccination with a composition comprising a phosphorylcholine (PC) and an adjuvant and the vaccination induces T15 antibody response (claims 1-19, col. 4-5). The '032 patent further teaches that the PC is the immunodominant epitope found on the surface of *Streptococcus pneumoniae* (Spn) and a polysaccharide of the cell wall component (lipoteichoic acid) is a major virulent factor of Spn.

Note that the claimed method is a "method of using the product-by process (e.g. synthetic vs. derived from a cell wall of a pathogen)"and the preparations used in the '032 patent and in the instant application are identical (e.g. PC-containing). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by different process. *In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964 966 (Fed. Cir. 1985). See MPEP 2113.

Where the claimed and prior art products are identical or substantially identical in structure or composition or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best* (562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada* (911 F.2d 705, 709, 15 USPQ 2d 1655, 1658 (Fed. Cir 1990). See MPEP 2112.01.

Given that the referenced and the claimed "phosphorylcholine enriched preparation" are essentially identical, the administration of the referenced composition inherently results in the production of antibodies that bind to oxidized low density lipoprotein (oxLDL) and inherently treats atherogenesis.

Therefore, the reference teachings anticipate the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-14 and 26-32 are rejected under 35 U.S.C. 103 as being unpatentable over WO 92/10203 in view of U.S. Pat. No. 5,455,032 and Shaw et al (J. Clnical. Invest., vol. 105, p. 1731-1740, IDS reference).

The '203 publication has bee discussed supra.

The disclosure of the '203 publication differs from the claimed invention in that it does not teach the use of phosphorylcholine derived from lipoteichoic acid of Spn as in claims 5 and 32 of the instant application.

The '032 patent teaches a method of vaccination with a composition comprising a phosphorylcholine (PC) and an adjuvant and the vaccination induces T15 antibody response (claims 1-19, col. 4-5). The '032 patent further teaches that the PC is the immunodominant epitope found on the surface of *Streptococcus pneumoniae* (Spn) and a polysaccharide of the cell wall component (lipoteichoic acid) is a major virulent factor of Spn (col. 4) and PC antibodies bind to Spn via the cell wall component. Moreover, the '032 patent teaches that the composition comprising PC provides immunization for pathogenic organisms having PC as a component of their cell wall capsids (col. 2).

Shaw et al. teach that T15 antibodies bind to various oxidized LDL (oxLDL) derived from 1-palmitoyl-2-oxovaleroyl-sn-glycero-3-phosphoryl-choline (POVPC) (p.1731). Shaw et al. further teach that T15 antibodies affect atherosclerosis by preventing foam-cell formation and deposition of oxidized LDL in the artery wall (p. 1739).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer PC preparation of lipoteichoic acid of Spn or from POVPC as taught by the '032 patent and Shaw et al. to inhibit atherogenesis.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because vaccinating with phosphorylcholine induces T15 antibody response and T15 antibody affects atherosclerosis by preventing foam-cell formation and deposition of oxidized LDL in the artery. Given that PC is an immunodominant epitope found on Spn and induces T15 antibody response which effectively removes oxidized LDL, using PC derived from a POVPC of Spn or lipoteichoic acid will provide more oxidation dependent epitopes (p. 1739).

Further, given that T15 antibodies affect atherosclerosis by preventing foam cell formation and deposition of oxidized LDL as per the teachings of Shaw et al., it would have been obvious to administer antibodies that bind oxidized lipoproteins such as the T15 antibodies of Shaw et al., to inhibit foam cell formation and oxLDL deposition. Thus, claims 9-12 have been included in this rejection.

From the teachings of references, it would have been obvious to one of ordinary skill in art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F, 9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
May 29, 2009

/Michael Szperka/
Primary Examiner, Art Unit 1644